

Attorney Docket No. 9286.7  
Application Serial No.: 10/019,902  
Page 14 of 17

### REMARKS

Claims 1-6, 8-12, 14-16, 18, 20, 23, 27 and 28 are pending in this application. Claims 1, 10, 12, 15, 18, 23, 27 and 28 are amended herein for clarity to more particularly define the invention. Applicants respectfully request entry of these amendments and reconsideration of this application in light of these amendments and the following remarks.

#### Support for Claim Amendments

The amendments presented above have been made to recite particular features of the invention so as to expedite the prosecution of the present application to allowance in accordance with the USPTO Patent Business Goals (65 Fed. Reg. 54603, September 8, 2000). These amendments do not represent an acquiescence or agreement with any of the outstanding rejections.

Claims 1, 10, 12, 15, 18, 23, 27 and 28 are amended herein to recite: "...( $A^2$ - $A^3$ ) can be any  $A^2$  and any  $A^3$  in any combination," Support for these amendments is found throughout the specification and in the original claim language. It is believed that no new matter is added by these amendments. The issues raised in the Office Action are addressed hereinbelow in the order in which they appear.

#### I. Information Disclosure Statement

The Examiner notes references listed on the International Search Report for the PCT that have not been listed on separate form PTO-1449. A Supplemental Information Disclosure Statement and PTO-1449 is being filed separately in order to make these references of record in the prosecution of the present application.

#### II. Drawings

Applicants amend herein the labels to Figure 1. A replacement sheet including Figure 1 is attached hereto. Applicants believe that the replacement sheet addresses the objections of the

Attorney Docket No. 9286.7  
Application Serial No.: 10/019,902  
Page 15 of 17

Examiner, however, should the changes not be accepted, Applicants solicit the Examiner for suggestions in order to address this matter.

### III. Claim Rejections - 35 U.S.C. § 112-Second Paragraph

Claims 1-6, 8-12, 14-16, 18, 20, 23, 27 and 28 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention.

Applicants amend herein claims 1, 10, 12, 15, 18, 23, 27 and 28 to indicate that  $A^2-A^3$  may be different within  $(A^2-A^3)_k$ . Applicants believe that the present amendment to the instant claims addresses the Examiner's rejection of these claims under 35 U.S.C. § 112, second paragraph, and Applicants respectfully request that the instant rejection be withdrawn.

### IV. Claim Rejections - 35 U.S.C. § 112-First Paragraph

Claims 1-6, 8-12, 14-16, 18, 20, 23, 27 and 28 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking enablement. Applicants respectfully traverse this rejection hereinbelow.

The Examiner alleges a high degree of unpredictability in the art given that some of the compounds described in the present application and in Tuzikov et al. (2003) *ChemBioChem* 4:147-154 do not associate and that it is unclear as to the characteristics required for aggregation of compounds and thus therapeutic advantage over the monomeric compounds.

Applicants assert that one of skill in the art can determine how the structural particularities of these compounds and external conditions, e.g., temperature, pH and presence of salts, affect the ability of the compounds to associate in a predictable and routine manner. Although the Examiner points out the third entry on Table 1 at page 14 as an example of a compound which has no increased activity is observed, Applicants point out that the instant compound (third entry on Table 1) is known not to associate in aqueous solution, but has been demonstrated to associate in non-aqueous solutions or in water on the virus surface. Furthermore, although Tuzikov et al. may point out that compounds with  $n < 6$  do not associate under particular conditions, association may and can take place under other conditions that can be

Attorney Docket No. 9286.7  
Application Serial No.: 10/019,902  
Page 16 of 17

determined by routine experimentation. Different conditions of association would be known to one of ordinary skill in the art and Applicants need only demonstrate the ability to associate in general in order to adequately enable this invention.

The Examiner further alleges that the examples of B defined by  $((A^2-A^3))$  are confined to glycine. Applicants disagree and direct the Examiner to example 5, and in particular to compounds #33, 34 and 35, which provide amino caproic acid (AC) as examples in addition to glycine. Applicants also have data confirming that other moieties having the formula  $NH_2(CH_2)_kCOOH$  can form a stable system of hydrogen bonds in "polyglycine II" associations. Thus the application provides a representative number of different B moieties to enable the full scope of B moieties in the claims.

Furthermore, the application provides adequate guidance to one of ordinary skill to make and evaluate compounds when k is about 7 or greater and such methods of making and evaluating are routine in the art. For example, Applicants have successfully synthesized tetraantennary molecules with  $k = 10$  and biantennary molecules with  $k \gg 10$ , demonstrating that undue experimentation is not required to make such compounds.

It is also indicated by the Examiner that the only experimental data are *in vitro* tests for influenza. In response, Applicants direct the Examiner to examples 8 and 11, wherein compound 49 of example 8 is shown to be a potent inhibitor of complement-dependent cytotoxicity as demonstrated in example 11.

In summary, Applicants point out that the present invention is based on the generic concept of providing polyvalent active agents dynamically coupling a ligand acceptor arrangement by intramolecular aggregates of defined low molecular weight species, thereby providing a drastic increase in the binding affinity and little risk for side effects. Insofar as the claims are directed to single compounds, the preparation and testing of such compounds is adequately described in the application and would not require undue experimentation. To the extent the claims are directed to aggregates, the preparation and testing of such aggregates is also adequately described in the specification and no undue experimentation would be required to make and use such aggregates.

In view of the foregoing, Applicants believe that the instant claims are enabled, and Applicants respectfully request the withdrawal of this rejection.

Attorney Docket No. 9286.7  
Application Serial No.: 10/019,902  
Page 17 of 17

### CONCLUSIONS

The points and concerns raised by the Examiner in the outstanding Office Action have been addressed in full, it is respectfully submitted that this application is in condition for allowance. Should the Examiner have any remaining concerns, it is respectfully requested that the Examiner contact the undersigned Attorney at (919) 854-1400 to expedite the prosecution of this application to allowance.

Applicants hereby authorize the Commissioner to charge Deposit Account No. 50-0220 in the amount of \$120.00 for a one month extension of time. Applicants believe that this amount is correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220

Respectfully submitted,

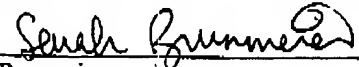


Mary L. Miller  
Registration No. 39,303

**USPTO Customer No. 20792**  
Myers Bigel Sibley & Sajovec, P.A.  
Post Office Box 37428  
Raleigh, NC 27627  
Telephone (919) 854-1400  
Facsimile (919) 854-1401

### CERTIFICATION OF FACSIMILE TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office via the central facsimile number 703-872-9306 on January 10, 2005.

  
\_\_\_\_\_  
Sarah Brunmeier